

Office Action Summary	Application No. 10/594,576	Applicant(s) SCHWARZ, THOMAS	
	Examiner MEI-PING CHUI	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☒ Claim(s) 5-8, 12-13 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>N/A</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Action

The Examiner acknowledges receipt of application number 10/594,576 filed on 06/28/2007. Accordingly, claims 1-19 are presented for examination on the merits for patentability.

Comments:

- (1) In claim 1, please insert --- "A" --- before "Formulation comprising..." (see claim 1, line 1). In claims 2-8, please insert --- "The" --- before "Formulation according to ..." (see claims 2-8, line 1).
- (2) In claim 1, please use the align format for the phrase "characterized in that" instead of the justify format (see claim 1, line 3).

Claim Objections

Claims 5-8, 12-13 and 18 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 2-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(1) **Claims 9-19** provide for the “use” of an osmolyte originating from extremophilic microorganisms; but the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. See MPEP, 2173.05(q).

Claims 9-19 are also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). See MPEP, 2173.05(q).

Notes to the applicants: once applicants amend the claims, restriction may be required depending on the amendment of the claims.

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(2) **Claims 2-8 and 11-13** are rejected 35 U.S.C. 112, second paragraph, because a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "parenthesis" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, **claims 2 and 11** recite the broad range of an osmolyte, which ranges from 0.05 to 10 % by weight of the formulation. However claim 2 and 11 also recite a narrower range for the osmolyte, which is between 0.1 to 5 % by weight. Similarly, **claim 4** recites a broad range of natural oils and fats, which ranges from 0.1 to 50 % by weight of the formulation. However claim 4 also recites a narrower range for the natural oils and fats, which is between 0.05 to 10 % by weight.

Claims 3, 5-8 and 12-13 are rejected because they depend from claims 2, 4 and 11, and thus incorporate its limitation.

- (3) **Claim 10** is rejected because it recites the limitation “between 0.01 and 50 % by weight in relation to the entire formulation” according to claim 9 (see line 2). There is insufficient antecedent basis for this limitation “the entire formulation” in the claim because independent claim 9 does not recite the term “formulation”.
- (4) **Claim 19** is rejected because it recites the term “vitamin derivatives”. The term “derivatives” is defined, according to Merriam-Webster’s Collegiate Dictionary (tenth Edition), as a chemical substance related structurally to another substance and theoretically derivable from it, or a substance that can be made from another substance (see page 311, derivative (n): meaning 4 and 5). However, the term “derivatives” is not defined by the claim, and the specification does not provide a standard for ascertaining the requisite degree; it is unclear that the term “derivative” means a structural derivative or a functional derivative in relation to the vitamin in the claim. Therefore, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, and thus rendering the claim indefinite.

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Claim Rejection - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102(b) that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-12 and 14-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Motitschke et al. (U. S. Patent No. 6,403,112).

The instant claims 1-4 and 6-13 are directed to a formulation comprising (i) natural oils and fats in an amount of 0.01 to 50 % by weight; (ii) osmolyte that is originating from extremophilic microorganism and is present in an amount 0.01 to 50 % by weight; (iii) unsaturated fatty acids; wherein the osmolyte is ectoine, hydroxyectoine, cDPG, DPG, firoid, firoid A or diinositol phosphate. The instant claims 14-19 are directed to a formulation comprising an osmolyte and at least one UV filter, enzymes, vitamins, vitamin derivatives or proteins; wherein the osmolyte is ectoine or hydroxyectoine.

With respect to claims 1-4, 6-7, 9-12, 14-17, Motitschke et al. disclose a cosmetic formulation comprising (S)-1,4,5,6-tetrahydro-2-methyl-4-pyrimidinecarboxylic acid (it is known as ectoine) and/or (S,S)-1,4,5,6-tetrahydro-5-hydroxy-2-methyl-4-

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pyrimidinecarboxylic acid (it is known as hydroxyectoine), which is found in extremely halophilic microorganisms (column 1, line 14-18).

Motitschke et al. also disclose that ectoine and its derivative, i.e. hydroxyectoine, is often used in cosmetic products as moisturizers to improve and stabilize the moisture content of the skin (column 2, line 51-54; column 1, line 21-24 and 44-46).

Motitschke et al. disclose that the cosmetic formulation comprises natural oils, i.e. vegetable oils, oily plant extracts, paraffin oils, lanolin oils, or mixtures thereof (column 6, line 25-30).

Motitschke et al. also disclose that the cosmetic formulation further comprises customary carriers, i.e. animal and vegetable fats (column 5, line 45-46); emulsifiers, i.e. cottonseed oil or olive oil (column 5, line 64-65), which are known to contain high content of unsaturated fatty acids, as well as glycerol fatty esters (column 5, line 66).

Motitschke et al. disclose that the active, i.e. ectoine or hydroxyectoine, is present in an amount of 0.1 to 10 % by weight, preferably in an amount of 0.1 to 3 % by weight of the formulation (column 6, line 35-38).

Motitschke et al. also disclose that the amount of natural oil, i.e. macadamia nut oil, is present in an amount of 2 % by weight, and fatty acid ester, i.e. glyceryl stearate, is present in an amount of 4 % by weight (column 7, Example 2, Table 1: ectoine emulsion). Therefore, the natural oil and fat is present in 6 % by weight in the emulsion.

Therefore, instant claims 1-4, 6-7, 9-12, 14-17 are anticipated.

With respect to claims 8 and 18, Motitschke et al. disclose that the cosmetic formulation, which is present in the form of solutions, suspensions, emulsions, pastes,

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ointments, gels, creams, lotions, powders, soaps, surfactant-containing cleansers, oils, sprays, lipsticks, lip salve sticks, mascara, eyeliner, blusher, powder foundation, emulsion foundation, wax foundation, sun care or after-sun preparations (column 5, line 32-35 and column 6, line 31-34). Therefore, instant claims 8 and 18 are anticipated.

With respect to claim 19, Motitschke et al. disclose the cosmetic formulation is prepared together with auxiliaries, i.e. vitamins, preservatives or antioxidants, for example (column 5, line 25-28 and 39-41). Therefore, instant claim 19 is anticipated.

With respect to the art rejection set forth above, it is noted that the reference of Motitschke et al. does not disclose that the formulation can be used in the manner instantly claimed in claims 7-9, 14-16 and 18; however, the intended use of the claimed formulation does not patentably distinguish the formulation, per se, such undisclosed use is inherent in the reference formulation. In order to be limiting, the intended use must create a structural difference between the claimed formulation and the prior art formulation. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motitschke et al. (U. S. Patent No. 6,403,112) in view of Marty, J.-P. (U. S. Patent No. 4,702,913).

Applicant Claims

The instant claims 5 and 13 are directed to a formulation comprising (i) natural oils and fats; (ii) osmolyte that is originating from extremophilic microorganism and is present in an amount 0.01 to 50 % by weight; (iii) unsaturated fatty acids; and (iv) evening primrose oil.

Determination of the scope and content of the prior art (MPEP 2141.01)

The teaching of Motitschke et al. has been set forth above. Essentially, Motitschke et al. teach a cosmetic formulation comprising (S)-1, 4, 5, 6-tetrahydro-2-methyl-4-pyrimidinecarboxylic acid (it is known as ectoine) and/or (S, S)-1, 4, 5, 6-tetrahydro-5-hydroxy-2-methyl-4-pyrimidinecarboxylic acid (it is known as hydroxyectoine), which is found in extremely halophilic microorganisms (column 1, line 14-18).

Motitschke et al. also teach that ectoine and its derivative, i.e. hydroxyectoine, is often used in cosmetic products as moisturizers to improve and stabilize the moisture content of the skin (column 2, line 51-54; column 1, line 21-24 and 44-46).

Motitschke et al. teach that the cosmetic formulation comprises natural oils, i.e. vegetable oils, oily plant extracts, paraffin oils, lanolin oils, or mixtures thereof (column 6, line 25-30).

Motitschke et al. also teach that the cosmetic formulation further comprises customary carriers, i.e. animal and vegetable fats (column 5, line 45-46); emulsifiers, i.e. cottonseed oil or olive oil (column 5, line 64-65), which are known to contain high content of unsaturated fatty acids, as well as glycerol fatty esters (column 5, line 66).

Motitschke et al. teach that the active, i.e. ectoine or hydroxyectoine, is present in an amount of 0.1 to 10 % by weight of the formulation (column 6, line 35-38).

***Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)***

Motitschke et al. do not specifically teach the oily plant extract use in the cosmetic formulation is evening primrose oil. However, the deficiency is cured by the teaching of Marty, J-P.

Marty, J.-P. teaches a cosmetic or dermatological composition comprising oenothera oil to retard skin aging effects (column 1, line 49-52).

Marty, J.-P. teaches that a deficiency of essential polyunsaturated fatty acids increases with aging that leads to dry skin, loss of elasticity and loss of transepidermal water. It is known that oenothera oil is particular rich in essential polyunsaturated fatty acids, namely, linoleic acid, γ -linolenic acid and arachidonic acid, and acts as a barrier to the skin to control the loss of water when applying to the skin. Thus, the application of oenothera oil, which contains said polyunsaturated fatty acids, enables the hydration of the skin to be conserved (column 1, line 64-67 and column 2, line 1-7).

Marty, J.-P. also specifically teaches the use of evening primrose oil (it is oenothera oil) in the composition (column 5, Example 5: creams A and C).

It is also noted that Marty, J.-P. teaches said composition can comprise vitamin extracts and a small quantity of solar radiation filters or sunscreens, i.e. UV-A and UV-B radiation filters (column 3, line 1-3 and 19).

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***Finding of prima facie obviousness Rational and Motivation
(MPEP 2142-2143)***

It would have been obvious to a person of ordinary skilled in the art at the time the invention was made to combine the teachings of Motitschke et al. and Marty, J.-P. to arrive at the instant claimed invention.

One of ordinary skill would have been motivated to utilize an oily plant extract, i.e. the evening primrose oil, in the cosmetic formulation with a reasonable expectation of success because the evening primrose oil (oenothera oil), which is obtained from the plant *Oleum Oenotherae*, is capable forming a skin barrier to prevent the loss of skin moisture, as taught by Marty, J.-P.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because the combined teachings of the prior art fairly suggests the instant claims, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication from the Examiner should direct to Helen Mei-Ping Chui whose telephone number is 571-272-9078. The examiner can normally be reached on Monday-Thursday (7:30 am – 5:00 pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where the application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either PRIVATE PAIR or PUBLIC PAIR. Status information for unpublished applications is available through PRIVATE PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the PRIVATE PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila Gollamudi Landau

Primary Examiner

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